BEST AVAILABLE IMAGES

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images may include (but are not limited to):

- BLACK BORDERS
- TEXT CUT OFF AT TOP, BOTTOM OR SIDES
- FADED TEXT
- ILLEGIBLE TEXT
- SKEWED/SLANTED IMAGES
- COLORED PHOTOS
- BLACK OR VERY BLACK AND WHITE DARK PHOTOS
- GRAY SCALE DOCUMENTS

IMAGES ARE BEST AVAILABLE COPY.

As rescanning documents *will not* correct images, please do not report the images to the Problem Image Mailbox.

What is Claimed is:

1. A pharmaceutical formulation to provide a unit dosage of amoxicillin and potassium clavulanate which comprises from 100 to 150 mg of potassium clavulanate and from 1700 to 2500 mg of amoxicillin; which formulation is a modified release formulation comprising an immediate and a slow release phase and in which all of the potassium clavulanate and from 0 to 50% of the amoxicillin is in an immediate release phase and from 50 to 100% of the amoxicillin is in a slow release phase; such that the mean T>MIC is at least 4 h for an MIC of 8 μg/ml.

2. A formulation as claimed in claim 1 in which the unit dosage comprises about 125 mg of potassium clavulanate.

3. A formulation as claimed in claim 1 in which the unit dosage comprises from 1900 to 2250, typically about 2000 mg of amoxicillin.

4. A formulation as claimed in claim 1 in which the unit dosage comprises about 2000 mg of amoxicillin.

5. A formulation as claimed in claim 1 in which the slow release phase comprises from 60 to 90 % of the total amoxicillin content.

6. A formulation as claimed in claim 1 in which the slow release phase comprises from 70 to 90, yet more preferably 76 to 90 % of the total amoxicillin content.

7. A formulation as claimed in claim 1 in which the slow release phase comprises from 76 to 90 % of the total amoxicillin content.

8. A formulation as claimed in claim 1 in which mean T>MIC is at least 4.2 h.

9. A formulation as claimed in claim 1 in which mean T>MIC is at least 4.4 h.

10. A formulation as claimed in claim 1 in which mean T>MIC is at least 4.6 h.

11. A formulation as claimed in claim 1 in which mean T>MIC is at least 4.8 h.

12. A formulation as claimed in claim 1 in which the unit dosage is selected from 1750/125, 2000/125, and 2250/125 mg of amoxicillin and potassium clavulanate, respectively.

13. A formulation as claimed in claim 1 in which the unit dosage is provided as from 2 to 4 tablets or capsules, a single dispersible tablet, a single chewable tablet which may also be effervescent and/or dispersible or a single dosage sachet.

14. A formulation as claimed in claim 1 in which the unit dosage is provided as 2 tablets or capsules comprising 1000/62.5 mg amoxicillin/potassium clavulanate or a single dispersible tablet, a single chewable tablet which may also be effervescent and/or dispersible or a single dosage sachet comprising 2000/125 mg amoxicillin/potassium clavulanate.

15. A pharmaceutical formulation of amoxicillin and potassium clavulanate which comprises from 50 to 75 mg of potassium clavulanate and from 850 to 1250 mg of amoxicillin or from 100 to 150 mg of potassium clavulanate and from 1700 to 2500 mg of amoxicillin; which formulation is a modified release formulation comprising an immediate and a slow release phase and in which all of the potassium clavulanate and from 0 to 60% of the amoxicillin is in an immediate release phase and from 40 to 100% of the amoxicillin is in a slow release phase; such that the parameter mean T>MIC is at least 4 h for an MIC of 8 μg/ml.

16. A pharmaceutical formulation as claimed in claim 15 which is a layered tablet formulation comprising potassium clavulanate and amoxicillin in an immediate release layer phase and amoxicillin in a slow release layer.

17. A pharmaceutical formulation as claimed in claim 16 which the slow release layer comprises a release retarding excipient selected from pH sensitive polymers; release-retarding polymers which have a high degree of swelling in contact with water or aqueous media such as the stomach contents; polymeric materials which form a gel on contact with water or aqueous media; and polymeric materials which have both swelling and gelling characteristics in contact with water or aqueous media.

18. A pharmaceutical formulation as claimed in claim 17 in which release retarding excipient is xanthan gum, preferably present in from 4 to 15% by weight of the layer.

19. A pharmaceutical formulation as claimed in claim 16 in which the slow release layer comprises a soluble salt of amoxicillin and a release retarding excipient which is a pharmaceutically acceptable organic acid.

20. A pharmaceutical formulation as claimed in claim 19 in which pharmaceutically acceptable organic acid is a fruit acid, for instance citric acid.

21. A pharmaceutical formulation as claimed in claim 15 which is a monolith tablet, a single dose sachet or granules comprising immediate release granules comprising amoxicillin and potassium clavulanate optionally with further immediate release granules comprising amoxicillin and slow release granules comprising amoxicillin and a release retarding excipient.

22. A method of treating a bacterial infection in a patient in need thereof which method comprises administering an effective amount of a formulation as hereinbefore defined, to a patient in need thereof, twice daily, preferably about every 12 h.